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Greater weight loss and regression to normoglycaemia, and reduced risk of T2D, at 3 years in early weight loss responders to liraglutide 3.0 mg vs early non-responders

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Abstract:

Background and aims: The SCALE Obesity and Prediabetes trial randomised adults with prediabetes and obesity (BMI ≥ 30 kg/m²) or overweight with comorbidities (≥ 27 kg/m²; dyslipidaemia / hypertension) to liraglutide 3.0 mg (N=1505) or placebo (N=749) as adjunct to diet and exercise for 3 years. This *post hoc* analysis compared liraglutide 3.0 mg early responders (ERs: $\geq 5\%$ weight loss at week 16) and early non-responders (ENRs: $< 5\%$ weight loss at week 16), in keeping with EMA stopping-rule criteria.

Materials and methods: Efficacy outcomes are estimated means in ERs (n=580) and ENRs (n=210) who completed 160 weeks of treatment. Those developing T2D or regressing to normoglycaemia were analysed on the full analysis set with LOCF. Safety was based on the safety analysis set (n=886 ERs, n=416 ENRs). Placebo data are shown only for proportion of ERs/ENRs.

Results: Of individuals with week 16 data, for liraglutide 3.0 mg (n=1302) 68.0% were ERs and 32.0% ENRs; for placebo (n=640), 22.3% were ERs and 77.7% ENRs. At week 160, greater mean and categorical weight loss and greater improvements in cardiometabolic risk factors and patient-reported outcomes were observed in ERs to liraglutide 3.0 mg vs ENRs (Table). At week 160 0.5% of ERs and 3.2% of ENRs had been diagnosed with T2D; 69.8% of ERs and 55.4% of ENRs had regressed to normoglycaemia while on treatment. Adverse events (AEs) were reported in 97.1% and 95.0% of ERs and ENRs, respectively; serious AEs in 17.7% and 12.7%; gastrointestinal AEs in 75.3% and 71.6%; and gallbladder disorders in 6.3% and 2.2%.

Conclusion: Among individuals treated with liraglutide 3.0 mg, over 160 weeks a reduction in diagnoses of T2D and greater regression to normoglycaemia were observed in ERs vs. ENRs while on treatment. Among those completing 160 weeks of treatment, greater weight loss and improvements in cardiometabolic risk factors and patient-reported outcomes were observed in ERs vs. ENRs. Apart from gallbladder related events, which may relate to greater weight loss in ERs, AE rates were similar between ERs and ENRs.

Table. Outcomes in ERs and ENRs who completed 160 weeks of treatment.

Week 0–160	Early responders to liraglutide 3.0 mg n=580	Early non-responders to liraglutide 3.0 mg n=210
Change in body weight (%)	–8.6	–2.9
Change in body weight (kg)	–9.1	–3.1
Proportion achieving ≥5% weight loss (%)	65.4	33.3
Proportion achieving >10% weight loss (%)	36.7	14.1
Proportion achieving >15% weight loss (%)	19.0	5.5
Change in FPG (mmol/L)	–0.43	–0.32
Change in HbA _{1c} (%)	–0.44	–0.33
Change in SBP (mmHg)	–3.74	–3.26
Change in SF-36 physical component summary score ^a	+3.68	+1.81
Change in IWQoL-Lite total score ^a	+13.40	+9.53

^aIncrease in score=improvement

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